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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,292	03/21/2001	De-Chao Yu	348022001500	4803

24353 7590 04/18/2003
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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

19

DATE MAILED: 04/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No.		Applicant(s)	
	09/814,292		YU ET AL.	
	Examiner		Art Unit	
	Gerald G Leffers Jr.		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/10/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 54, 56, 58-61, 63-70, 78, 79, 82, 83 and 104-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 54, 56, 58-61, 63-70, 78, 79, 82, 83 and 104-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 2/10/03 as Paper No. 18, in which several claims were amended (claims 1-5, 54, 61, 63-66, 68, 70, 78-79, 82-83). Claims 1-5, 54, 56, 58-61, 63-70, 78-79, 82-83 and 104-107 are pending in the instant application.

Any rejection of record in the previous action (Paper No. 17, mailed 11/05/02) that is not addressed herein is withdrawn. This action is not final due to a new grounds of rejection made herein that was not necessitated by applicants' amendment of the claims in Paper No. 18.

Specification

The disclosure is objected to because of the following informalities: the Brief Description of the Drawings indicates that Figure 2 shows an asterisk at the translational start site of SEQ ID NO: 2. No such indication of the translational start site is present in Figure 2.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 54, 56, 58-61, 63-70, 78-79, 82-83 and 104-107 are rejected under 35

U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

Each of the claims recites a limitation of a "uroplakin II (UPII) transcriptional regulatory element (TRE)" that comprises specific nucleotide sequences described in SEQ ID NO: 1 or SEQ ID NO: 2. Many of the claims are directed towards adenoviral vectors comprising an adenoviral gene essential for replication under transcriptional control of the uroplakin II (UPII) transcriptional response element (TRE). The specification teaches that the term "transcriptional response element" refers to a promoter or enhancer that increases transcription of an operatively linked polynucleotide sequence (page 14, lines 13-18). A reasonably broad interpretation of the words "uroplakin II TRE" encompasses additional transcriptional regulatory elements (TREs) that are associated with the human and murine uroplakin II genes that respond under different conditions in urothelial cells (e.g. at different times during urothelial cell development) that are not present within SEQ ID NOS: 1 or 2. The claims also reasonably encompass synthetic TREs that comprise additional elements derived from homologs of UPII obtained from other sources that are not identical to those described in the specification (i.e. SEQ ID NOS: 1-2). Because the rejected claims are drawn towards a UPII TRE comprising sequences described in SEQ ID NO: 1 or 2, the rejected claims still encompass a very large number of potential TRE sequences.

The specification teaches only two sequences from two different sources that are considered to be TRE sequences associated with uroplakin II genes (i.e. from human and mouse). The specification does not provide a basis for one to extrapolate structural/functional characteristics of these sequences to other potential TRE sequences associated with uroplakin II genes obtained from alternative sources. The specification does not provide a basis for one to

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extrapolate structural/functional characteristics of these sequences to other potential TRE sequences associated with the human and mouse uroplakin II genes that act to increase expression of the uroplakin II genes during different conditions (e.g. during different stages of animal development).

The prior art does not appear to teach the characterization of all of the human and/or mouse uroplakin II TRE elements that are required for expression under different conditions (e.g. during embryonic development, old age, etc.). The prior art does not appear to teach TRE elements from uroplakin II genes from alternative mammalian sources. Therefore, the prior art does not offset the deficiencies of the instant specification with regard to describing the broadly claimed genus of TRE elements.

Given the very large number of potential uroplakin II TRE sequences encompassed by the rejected claims and give the lack of a basis provided by the instant specification or prior art for envisioning TRE elements associated with uroplakin II genes that are not homologous to the human or mouse sequences described in the specification, one of skill in the art would not have been able to envision a representative number of specific embodiments to describe the broadly claimed genus of such uroplakin II TRE sequences. Therefore, one of skill in the art would have reasonably concluded that applicants were not in possession of the claimed invention.

Response to Arguments

Applicant's arguments filed in Paper No. 18 have been fully considered but they are not persuasive. In Paper No. 18 applicants have amended the claims to recite specific sequences from SEQ ID NO: 1 or SEQ ID NO: 2. The response essentially argues that these amendments

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obviate the outstanding rejection. This assertion is not accurate in that the open claim language wherein the uroplakin II TRE comprises the recited sequences leaves open 1) additional response elements associated with the human and murine genes that are not described by SEQ ID NO: 1 or 2, and 2) synthetic TREs comprising additional UPII TREs obtained from additional sources that aren't homologous to the sequences recited in SEQ ID NO: 1 or SEQ ID NO: 2. It would be remedial to amend the claim language to have closed claim language with regard to the UPII TRE element (e.g. "a uroplakin II TRE consisting of nucleotides 2028-2239 of SEQ ID NO: 1").

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54, 56, 58-70, 72-76, 78-79, 82-83 and 104-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 54 and 70 refer to negative and positive nucleotides of SEQ ID NO: 2. No such indications are present in SEQ ID NO: 2 in the sequence listing (e.g. nucleotides -587 to +1). It would be remedial to amend the claim language to recite the intended limitation in terms of the sequence as it actually appears in the sequence listing. This also would provide a convenience for practitioners attempting to determine the exact metes and bounds of the invention.

Conclusion

No claims are allowed.

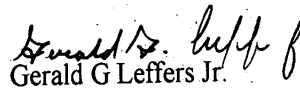
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232.

The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl
April 17, 2003